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John M. Howell 33,713
Name of Attorney/Agent Registration No.

John M. Howell
Signature of Attorney/Agent

Case 7804

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of :

DOUGLAS J. DOBROZSI ET AL. :

Serial No.: 09/467,333 :

Group Art Unit: 1614

Confirmation#: 2248 :

Filed: December 20, 1999 :

Examiner:

For: Compositions Having Improved Stability

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner For Patents

Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made below in a Form PTO-1449 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO-1449 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. ☐ 37 C.F.R. §1.97 (b)(1) - U.S. Direct (within 3-months of filing a regular application or converted provisional)

This information disclosure statement, submitted under 37 C.F.R. §1.97 (b)(1), is being filed within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2. ☐ 37 C.F.R. §1.97 (b)(2) - Via PCT (within 3 mo. of Nat'l Stage Entry)

This information disclosure statement, submitted under 37 C.F.R. §1.97 (b)(2), is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application. Therefore, no fee is believed to be due.

3. ☐ 37 C.F.R. §1.97 (b)(3) - (>3 mo. after filing direct or nat'l stage entry, but before 1st O.A.)

This information disclosure statement is being submitted under 37 C.F.R. §1.97 (b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to

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be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter is enclosed to facilitate charging of the fee, if necessary.

THE FOLLOWING IS ADDITIONAL INFORMATION PERTAINING TO (2) OR (3) MARKED WITH AN (X) ABOVE.

(a) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 indicates that both a copy of the International Search Report and copies of the references cited therein are present in the national stage file. In accordance with MPEP §1893.03(g), it is respectfully requested that the Examiner note the consideration of these references in the first Office Action via the PTO-892 form.

(b) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 indicates that a copy of the International Search Report is present in the national stage file. Copies of the references cited in that report are enclosed. It is respectfully requested that the Examiner note the consideration of these references in the first Office Action via the PTO-892 form.

(c) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 does not indicate that a copy of the International Search Report and copies of the references cited are present in the national stage file. Copies of the International Search Report and references are attached.

4. ☒ 37 C.F.R. §1.97(c) with fee payment - (use after 1st Office Action & before Final Office Action or Notice of Allowance)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113 or a notice of allowance under 37 C.F.R. §1.311 as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter is enclosed to facilitate the charging of the fee.

ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:

☐ (1) Copies of the cited references were previously cited by or submitted to the USPTO in prior application Case No. ___, U.S. Patent Application Serial No. ___, filed ___. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of those documents are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d).

OR

☒ (2) Copies of the cited documents are enclosed.

OR

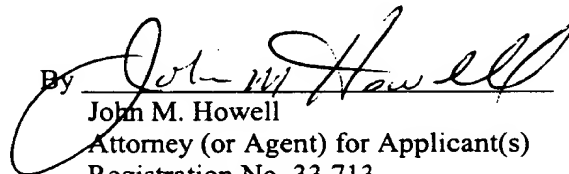
☐ (3) Copies of all said documents, except document No.'s _____, were submitted and considered in parent application U.S. Patent Application Serial No. _____, filed _____. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of document No.'s _____ are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of document No.'s _____ are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

☐ (4) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is on the attached page, except where a full English language translation is provided.

☐ (5) Applicants also respectfully request the Examiner to consider and make of record the copending applications listed on the attached page.

☐ Additional information is attached.

Respectfully submitted,

By 
John M. Howell
Attorney (or Agent) for Applicant(s)
Registration No. 33,713
(513) 622-2184

January 26, 2001
Health Research Center
Mason, OH 45040

JMH:lrs (cases/7804P/7804-IDS.doc)
(IDS.doc)
(Last Revised 3/23/2000)

Sheet 1 of 1

LIST OF DOCUMENTS CITED BY APPLICANTS (Use several sheets if necessary)	ATTY. DOCKET NO. 7804	SERIAL NO. 09/467,563
	APPLICANT Dobrozsi et al.	
	FILING DATE December 20, 1999	GROUP 14

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE APPROPRIATE
	6,110,846	8/29/00	Dugger, III	424	435	
	5,955,098	9/21/99	Dugger, III	424	435	
	5,458,879	10/17/95	Singh et al.	424	400	
	5,196,436	3/23/93	Smith	514	289	
	5,100,898	3/31/92	Sorrentino	514	281	
	5,196,486	3/23/93	Stephenson	525	328.8	
	4,232,002	11/04/80	Nogrady	424	45	
	4,136,163	1/23/79	Watson et al.	424	54	
	4,032,661	6/28/77	Rowsell et al.	424	337	
	4,459,425	7/10/84	Amano et al.	568	666	
	4,839,176	6/13/89	Pankhania et al.	424	465	
	4,474,985	10/2/84	Keel et al.	564	216	
	4,478,822	10/23/84	Haslam et al.	424	78	
	4,474,752	10/2/84	Haslam et al.	424	78	

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES NO
WO 95/19759	7/27/95	World	A61K	47/10	x
WO 95/23595	9/8/95	World	A61K	9/48	x
WO 96/23486	8/8/96	World	A61K	9/00	x
WO 98/52545	11/26/98	World	A61K	9/20	x
WO 95/04527	2/16/95	World	A61K	31/165	x
WO 94/18970	9/1/94	World	A61K	31/44	x
WO 99/16417	4/8/99	World	A61K	9/00	x
EP0295941A2	12/21/88	Europe	A61K	9/10	x
WO 93/00072	1/7/93	World	A61K	9/48	x

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Lund, "Stability of Medicinal Products", The Pharmaceutical Codex, pp. 277-310, Editor: W. Lund, 12 th Edition, The Pharmaceutical Press, London (1994).
	Harris et al., "Drug Deliver Via the Mucous Membranes of the Oral Cavity", J. of Pharmaceutical Sciences, Vol. 81, No. 1, pp. 1-10 (1992).
	Char et al., "Nasal Deliver of [¹⁴ C]Dextromethorphan Hydrochloride in Rats: Levels in Plasma and Brain", J. of Pharmaceutical Sciences, Vol. 81, No. 8, pp. 750-752 (1992).
	Martin et al., "Physical Chemical Principles in the Pharmaceutical Sciences", Physical Pharmacy, p. 237, Editor: G. H. Mundorff, 4 th Edition, Lea & Febiger, Philadelphia, London (1993).
	Wells, "Drug Stability", Pharmaceutical Preformulations: The Physicochemical Properties of Drug Substances, pp. 168-172, John Wiley & Sons, NY (1988).
	Hoffman et al., "Catecholamines, Sympathomimetic Drugs, and Adrenergic Receptor Antagonists", Goodman & Gilman's The Pharmacological Basis of Therapeutics, Chapter 10, pp. 221-224, 9 th Edition, McGraw-Hill (1996).
	Catterall et al., "Local Anesthetics", Goodman & Gilman's The Pharmacological Basis of Therapeutics, Chapter 15, pp. 331-347, 9 th Edition, McGraw-Hill (1996).
	Reisine et al., "Opioid Analgesics and Antagonists", Goodman & Gilman's The Pharmacological Basis of Therapeutics, Chapter 23, pp. 551-552, 9 th Edition, McGraw-Hill (1996).
	Babe et al., "Histamine, Bradykinin, and Their Antagonists", Goodman & Gilman's The Pharmacological Basis of Therapeutics, Chapter 25, pp. 581-600, 9 th Edition, McGraw-Hill (1996).
	Insel, "Analgesic-Antipyretic and Antiinflammatory Agents and Drugs Employed in the Treatment of Gout", Goodman & Gilman's The Pharmacological Basis of Therapeutics, Chapter 27, pp. 617-657, 9 th Edition, McGraw-Hill (1996).
	"Iodides" pp. 252-253, Drugs in Bronchial Mucology, Eds. P. C. Braga, M.D. and L. Allegra, M.D., Raven Press, NY (1989).
	"Sol-Layer and Mucus Hydration" pp. 309-312, Drugs in Bronchial Mucology, Eds. P. C. Braga, M.D. and L. Allegra, M.D., Raven Press, NY (1989).
	Rote Liste, No. 23140, "Bisolvon-Linctus cough syrup", (with translation by Ralph McElroy Translation Co.) (1994).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Patent and Trademark Office - U.S. DEPARTMENT OF COMMERCE